

**REMARKS**

With this Reply and Amendment, Claims 1, 10 and 17 have been amended, Claims 9 and 24 have been canceled without prejudice and no Claims have been added. Thus, after entry of this Reply and Amendment, Claims 1-8 and 10-23 are pending in the instant Application. Applicants expressly reserve the right to prosecute Claims to canceled subject matter in one or more continuation, divisional and/or continuation-in-part applications.

**AMENDMENT OF CLAIMS**

The amendment of Claims 1 and 17 is supported by originally filed Claims 9 and 24, respectively. The amendment of Claim 10 is supported by the Specification at page 1, line 11.

No new matter is added by amendment of Claims 1, 10 and 17. Accordingly, entry into the instant application is kindly solicited.

**REJECTION UNDER 35 U.S.C. § 112, first paragraph**

Claims 4-8 and 19-22 stand rejected under 35 U.S.C. § 112, first paragraph because the Specification, for allegedly not providing enablement for a 0.03% wt% composition of IB-367. Accordingly, the Patent Office alleged that the Specification failed to enable any person skilled in the art to which it pertains or with which it is most nearly connected, to make and use the invention commensurate in scope with the claims. Applicants respectfully traverse the rejection.

In order to satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph a patent application, supplemented with information known in the art, need only teach one of ordinary skill in the art how to make and use the invention, without conducting undue experimentation. The patent disclosure is not required to teach, and preferably omits that which is well known in the art. *In re Buchner* 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.* 231 USPQ 81, 94 (Fed. Cir. 1986); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.* 221 USPQ 481, 489 (Fed. Cir. 1984). Experimentation typically engaged in by those of skill in the art is permitted, as long as the experimentation is not undue. *In re Wands* 8 USPQ2d 1400, 1404 (Fed. Cir. 1988); *In re Angstadt* 190 USPQ 214, 219 (CCPA 1976).

The Examiner's attention is directed to page 7, second paragraph, lines 4-5 for specific enabling support for claims 4-8 and 19-22. With regard to the *In re Wands* factors, Applicants submit that the disclosure readily establishes enough information to avoid undue experimentation by providing sufficient guidance.

In view of the foregoing, Applicants respectfully request that the rejection of Claims 4-8 and 19-22 under 35 U.S.C. § 112, first paragraph be withdrawn.

**REJECTIONS UNDER 35 U.S.C. § 112, second paragraph**

Claims 1-24 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicants traverse the rejections.

With regard to the allegation that the metes and bounds of the limitation “an amount effective to prevent the infection” are unclear and thus render Claims 1 and 17 indefinite, Applicants point out that the limitation has been amended to recite “an amount effective to prevent ventilator associated pneumonia” Applicants submit that those of skill in the art can determine specific values for the “amount amount effective to prevent ventilator associated pneumonia” based on the disclosure, including the examples (See *e.g.*, Specification, page 7, and Examples 6.2 and 6.3). *In re Mattison* 184 USPQ 484 (CCPA 1975); *In re Halleck* 164 USPQ 647 (CCPA 1970). Accordingly, Applicants maintain that the limitation “an amount effective to prevent ventilator associated pneumonia” does not render Claims 1 and 17 indefinite.

With regard to the allegation that the term “essentially” is a relative term that renders Claims 2, 11, and 17 indefinite, Applicants point out that as used in Claims 2, 11 and 17, “essentially” is part of the well-known transitional phrase “consisting essentially thereof,” which defines the scope of a claim with respect to what unrecited additional components are excluded from the claim scope. *In re Herz* 190 USPQ 461, 463 (CCPA 1976); MPEP § 2111.03. Accordingly, Applicants submit that the use of the transitional phrase “consisting essentially thereof,” fails to render Claim 2, 11 and 17 indefinite.

With regard to the allegation that the term “about” is a relative term that renders Claims 4 and 19 indefinite, Applicants submit that claim language that which uses terms of degrees does not automatically render the claim indefinite under 35 U.S.C. § 112, second paragraph. *Seattle Box Co. v. Industrial Crating & Packaging*,

*Inc.* 221 USPQ 1568 (Fed Cir. 1984); MPEP § 2173.05 (b). Applicants assert that the term “about” is “clear but flexible” and is similar in meaning to terms such as “approximately” or “nearly.” *Ex parte Eastwood* 163 USPQ 316 (Bd. App. 1968). Accordingly, Applicants maintain those of ordinary skill in the pharmaceutical arts would be reasonably be apprised of the scope of the Claims 4 and 19.

With regard to the allegation that the abbreviation “VAP” renders Claims 9, 10 and 24 indefinite, Applicants have canceled Claims 9 and 24 and have amended Claim 10 to replace “VAP” with ventilator associated pneumonia.

With regard to the allegation that the limitation “the accessible portion of an endotracheal tube” lacks antecedent basis thus rendering Claims 8 and 23 indefinite, Applicants point out that “the accessible portion of an endotracheal tube” is an inherent component of the element “intubated” which is recited in Claims 1 and 17, from which Claims 8 and 23 depend respectively. Accordingly, “the accessible portion of an endotracheal tube” has antecedent basis. *Bose Corp. v. JBL, Inc.*, 61 USPQ2d 1216, 1218-19 (Fed. Cir 2001); MPEP § 2173.05 (e).

Claims 3, 5, 7, 12-16 and 18-22 were rejected as depending from indefinite Claims 1, 4, 10 and 17. Applicants have shown above that Claims 1, 4, 10 and 17 are definite. Accordingly, Claims 3, 5, 7, 12-16 and 18-22 are definite for at least the same reasons.

In view of the foregoing, Applicants respectfully request that the rejection of Claims 1-24 under 35 U.S.C. § 112, second paragraph be withdrawn.

#### **REJECTION UNDER 35 U.S.C. § 102 (b)**

Claims 1, 2, 4, 7, 17, 19 and 22 stand rejected under 35 U.S.C. § 102 (b) as being anticipated by Steinberg *et al.*, International Publication No. WO 00/04915 (hereinafter “Steinberg”). Applicants respectfully traverse the rejection.

Anticipation of a claim requires that the reference teach every element of the claim. MPEP § 2131. Thus, “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California* 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The limitation of claim 9 (which the Examiner found was not anticipated by Steinberg) has been inserted into claims 1 and 17. Thus, the present invention is a

method of preventing *ventilator associated pneumonia* associated with intubation or mechanical ventilation. A composition comprising an IB-367 peptide or a pharmaceutically acceptable salt thereof, is topically applied in an amount effective to prevent ventilator associated pneumonia to the oral cavity of a patient that is either intubated or about to be intubated.

The Examiner apparently agrees that Steinberg fails to teach or suggest that a composition comprising an IB-367 peptide or a pharmaceutically acceptable salt thereof can be topically applied in an amount effective to prevent ventilator associated pneumonia to the oral cavity of a patient that is either intubated or about to be intubated. Therefore, Steinberg fails to teach each and every element of the claimed invention. Accordingly, since Steinberg does not teach each and every element of the claimed invention the cited reference fails to anticipate the claimed invention.

In view of the foregoing, Applicants respectfully request that the rejection of Claims 1, 2, 4, 7, 17, 19 and 22 under 35 U.S.C. § 102 (b) be withdrawn.

**REJECTION UNDER 35 U.S.C. §§ 102 (a) /103 (a)**

Claims 1-24 stand rejected under 35 U.S.C. § 102 (a) as anticipated by or in the alternative under 35 U.S.C. § 103 (a) as being obvious over Kollef *et al.*, “Phase I Safety and Microbial Kinetic Study of Oral-Topical IB-367 Rinse and Gell in Intubated Patients Receiving Mechanical Ventilation” (hereinafter “Kollef”). Applicants respectfully traverse the rejection.

The Applicants submit herewith a Declaration under 37 CFR § 1.132 which establishes that Rebecca Redman is the sole inventor of the subject matter described in the Kollef, *et al.* reference. Accordingly, since Kollef *et al.*, was published less than one year before the filing date of the current application the cited reference is not prior art under 35 U.S.C. §§ 102 (a)/103 (a) against the instant patent application. *In re Katz* 215 USPQ 14 (CCPA 1982)

In view of the foregoing, Applicants respectfully request that the rejection of Claims 1-24 under 35 U.S.C. §§ 102 (a)/103 (a) be withdrawn.

**CONCLUSION**

Applicants respectfully submit that all pending Claims of the captioned Application satisfy all requirements for patentability and are in condition for allowance. An early indication of the same is therefore respectfully requested.

No fees are believed due in connection with this Reply. However, the Commissioner is authorized to charge any required fee not included with this Reply or credit any overpayment to Cooley Godward LLP Deposit Account No. 03-3117.

If the Examiner determines that prosecution of the instant application would benefit from a telephone interview, the Examiner is invited to call the undersigned attorney at (650)-843-5876.

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